

Bedrijfsgevoeligde informatie

Subject: Advisory notice

Hattemerbroek, November 17, 2023

Advisory notice regarding the possible presence of blocked connectors

Dear customer,

It recently emerged that an error occurred during the injection moulding process of one of the filter connectors we use (figure 1). A relatively small part of these connectors appears to be impenetrable and is blocked from the inside by an occluding fleece (figure 2). These faulty connectors may have ended up in some of our medical devices. There is no immediate danger to the patient, but the product will not function because gas cannot flow through it. A blocked connector will cause discomfort during use and will delay the procedure using the medical device in question.



Figure 1: Filter connector

Figure 2: Incorrect filter connectors with occluding fleece

We are currently working to inventory the number of incorrectly produced connectors. The preliminary estimate is that the number of defective products will be small, relatively speaking.

The attached list (Appendix A) provides an overview of the medical devices and lot numbers in which these connectors may be incorporated.

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Before using the products mentioned, we request that you check whether the connector is open. If you encounter a blocked connector, please report this to us as soon as possible.

If you have any questions, please send an email to <u>mailto:qa@dispomedical.nl</u>. We will answer your question as soon as possible.

Our sincere apologies for any inconvenience experienced.



Bedrijfsgevoeligde informatie



Annendix A List of	make which he affected	I mua durata unita tha	relevant lot numbers
ADDENDIX A – LISLOF	potentially affected	i producis with the	relevant for numbers
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REF	Description	LOT#
19087	Insufflation Tube with filter 300 cm MLL/TP	0923143
22795	Insufflation Tube + Connector	0923081
		0823195
31022	Insufflation Tube 22 mm 3.7m	0923304
		0823127
45243	Bacterial Filter	1023110
		0923179
		0723103
50116 Insuff	Insufflation Tube 22 mm	0923004
		0923018
		0723211
		0723039
		0623323
		0623208
		0823047
50156	Insufflation Tube 22 mm 3.7m	0923216
	Considerate Reconductional association. Understand association and a scalar international parts	0923152
		0923015
		0823051
		0723059
		0723175
		0723041
		0623325
		0623212
		0623308
59252	5 mm Duffnerset	0823083
10-092.300.510405415 7. 07 P	Desufflation Tube 425 cm	0923218
	inscription of property and a contraction of the process of the proces	0923010
		0723218
		0723061
		0723043
	F	0623213
		1023097
73272	Bacterial Filter Slime Line	0923299
		0823275
	1	0823185
78276	Insufflation Tube 22 mm	0823026
		0623117
78282	InsufflationTube + Connector	0923277

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